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111TH CONGRESS
2D SESSION

H. R. 5440

To secure the promise of personalized medicine for all Americans by expanding and accelerating genomics research and initiatives to improve the accuracy of disease diagnosis, increase the safety of drugs, and identify novel treatments, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 27, 2010

Mr. KENNEDY (for himself and Ms. ESHOO) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To secure the promise of personalized medicine for all Americans by expanding and accelerating genomics research and initiatives to improve the accuracy of disease diagnosis, increase the safety of drugs, and identify novel treatments, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

(a) SHORT TITLE.—This Act may be cited as the ''Genomics and Personalized Medicine Act of 2010''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. DEFINITIONS.

In this Act:

(1) BIOBANK.—The term ''biobank'' means a shared repository of human biological specimens collected for medical or research purposes that may include biobank data.

(2) BIOBANK DATA.—The term ''biobank data''—

(A) means data associated with a human biological specimen stored in a biobank collected for medical or research purposes; and

(B) includes, if feasible, health information, demographic, genotype, and molecular profile data, and environmental data associated with a specimen.

(3) BIOMARKER.—The term ''biomarker'' means a substance or chemical constituent found in or derived from a human biological specimen that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention.

(4) ENVIRONMENT; ENVIRONMENTAL.—The terms ''environment'' and ''environmental'' refer to conditions or circumstances that are nongenetic, but may have a health impact and affect the expression of genes.

(5) CEGAPP.—The term ''CEGAPP'' means the Committee on the Evaluation of Genomic Applications in Practice and Prevention established under section 211.

(6) CLIA.—The term ''CLIA'' means section 353 of the Public Health Service Act (42 U.S.C. 18

263a; commonly referred to as the ''Clinical Laboratory Improvement Amendments of 1988'').

(7) COMPANION DIAGNOSTIC TEST.—The term ''companion diagnostic test'' means a genetic or genomic test used in conjunction with a specific treatment that measures and evaluates a specific biomarker as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention for an individual's condition.

(8) GENETIC AND GENOMIC TESTS.—

(A) IN GENERAL.—The term ''genetic or genomic tests'' means analyses of human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene products (such as enzymes and other types of proteins), or metabolites, that—

(i) are predominately used to detect hereditable or somatic mutations, genotypes, or phenotypes related to disease and health; and

(ii) may be used to screen newborns, identify carriers of inherited mutations, predict risk of disease, establish prenatal or clinical diagnoses, provide prognostic in-

formation, diagnose malignancies, guide clinical management, identify targets for therapy, monitor results to therapy, and evaluate for early relapse.

(B) EXCLUSIONS.—The term ''genetic and genomic tests'' excludes—

(i) tests conducted exclusively for forensic and identity purposes;

(ii) tests conducted purely for research purposes;

(iii) tests that are used primarily for other purposes but that may contribute to diagnosing a genetic disease or disorder (such as blood smears and certain serum chemistries);

(iv) an analysis of proteins or metabolites that does not indicate genotypes, mutations, or chromosomal changes; or

(v) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

(9) HUMAN BIOLOGICAL SPECIMEN.—The term ''human biological specimen'' means any human body fluid, tissue, blood, or cell; any material derived from any human body fluid, tissue, blood, or cell; and, as feasible, any data associated with such specimens including associated health information, demographic, genotype, and molecular profile data, and environmental data.

(10) OPH.—The term ''OPH'' means the Office of Personalized Healthcare established under section 101.

(11) PERSONALIZED MEDICINE.—The term ''personalized medicine'' means any clinical practice model that emphasizes the systematic use of preventive, diagnostic, and therapeutic interventions that use genome and family history information to improve health outcomes.

(12) PHARMACOGENOMICS.—

(A) IN GENERAL.—The term ''pharmacogenomics'' means the study of individual variations in DNA and RNA characteristics and sequences and the relationship of such variations to drug response, including absorption, distribution, metabolism, and elimination (pharmacokinetics) or drug action

(pharmacodynamics). Such variations include nucleotide polymorphism rearrangements, insertions, and deletions. Such variations may also include alterations in gene expression or inactivation in the genes encoding drug transporters, receptors, metabolizing enzymes, or any other proteins that are implicated in pharmacological function and therapeutic response.

(B) VARIATIONS.—For purposes of this paragraph, the variations referred to in subparagraph (A) may affect a single nucleotide or more than one region in a single gene or reflect alterations in more than one gene.

(13) SACGHS.—The term ''SACGHS'' means the Secretary's Advisory Committee on Genomics, Health, and Society.

(14) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

TITLE I—OFFICE OF PERSONALIZED HEALTHCARE

SEC. 101. OFFICE OF PERSONALIZED HEALTHCARE.

(a) IN GENERAL.—The Secretary shall establish the Office of Personalized Healthcare within the Office of the Secretary.

(b) DIRECTOR.—The OPH shall be headed by a director, to be appointed by the Secretary.

(c) PURPOSE.—The purpose of the OPH is to coordinate the activities related to genomics and personalized medicine of the Department of Health and Human Services with those of other relevant agencies and public and private entities to ensure that personalized medicine meets the highest standards of safety, efficacy, and clinical validity and utility.

(d) DUTIES.—The Secretary, acting through the Director of the OPH, shall coordinate cross-agency activities and collaboration of the Department of Health and Human Services related to genomics and personalized medicine, and shall work with relevant departments and agencies and representatives of the private sector to—

(1) develop a strategic, long-term plan to advance research and development relevant to personalized medicine for coordinating basic science and translational research in personalized medicine;

(2) identify, prioritize, and address challenges in translational research on products used for personalized medicine, including genetic and genomic tests that impact both product development and regulation, including any ongoing initiatives;

(3) assure that coverage and reimbursement decisions for products used for personalized medicine take into account the best data available for such decisions without violating the data sharing constraints;

(4) identify and prioritize gaps in the evidence base concerning outcomes and cost-effectiveness of genomics-based diagnostics and to develop research or consensus development initiatives to address those gaps;

(5) clarify and simplify the regulation of products used for personalized medicine to ensure that guidelines are consistent and intra-agency regulations do not conflict;

(6) educate and consult with developers of products used for personalized medicine concerning evidence requirements for reimbursement and regulatory purposes, to facilitate development of more cost-effective clinical trial programs for new products;

(7) ensure that the Federal regulatory approach to information technology-based clinical decision support systems is evidence based and appropriately targeted;

(8) leverage and network existing agency and private sector expertise to address the needs in translating genomics into the implementation and practice of personalized medicine, including the findings and recommendations of the SACGHS and CEGAPP or any other such council or committee established for the purpose of advising the Secretary on personalized medicine; and

(9) provide a forum and mechanism to coordinate across agencies and the private sector with regard to discussing genomics priorities and the standards needed for personalized medicine to become feasible.

(e) ANNUAL REPORTS.—Not later than 24 months after the date of the enactment of this Act, and annually after submission of the initial report, the Director of the OPH shall prepare and submit to the appropriate committees of the Congress a report. Each such report shall describe—

(1) progress of cross-agency coordination related to personalized medicine;

(2) innovations in genomics and personalized medicine;

(3) emerging and persistent challenges related to personalized medicine;

(4) key barriers in research, regulation, and reimbursement and their impact on innovation, development, and implementation of medical product development for personalized medicine;

(5) medical, ethical, legal, and social impacts of personalized medicine; and

(6) the extent to which the findings and recommendations of the SACGHS, CEGAPP, and other Federal entities are used to inform policymaking on personalized medicine within the Department of Health and Human Services.

(f) REPORT ON THE REGULATION OF PRODUCTS USED FOR PERSONALIZED MEDICINE.—Not later than 18 months after the date of the enactment of this Act, the Director of the OPH shall submit to the Secretary and the appropriate committees of the Congress, and publish a report on, recommendations for the regulation of products used for personalized medicine (including genetic and genomic tests). Such report shall include recommendations regarding—

(1) which products used for personalized medicine should require regulation, and, for such products which are recommended in the report to require regulation, recommendations regarding—

(A) the appropriate regulatory submission requirements and timeframes for such submissions;

(B) the appropriate level of evidence necessary for approval of such products; and

(C) resubmission requirements for those products used for personalized medicine that undergo modifications;

(2) a clear delineation between the roles and responsibilities of the Food and Drug Administration and the Centers for Medicare & Medicaid Services in regulation and enforcement of products used for personalized medicine, including laboratory-developed tests, and the resolution of any conflicts or redundancies between the 2 agencies, including under section 401;

(3) a means by which to decrease the burden associated with the initial and subsequent submission of any required regulatory documents by clinical laboratories; and

(4) an evaluation of any current Federal registries for products used for personalized medicine (including those for genetic and genomic tests) to determine the appropriateness of establishing a mandatory registry for such products (including specific

recommendations pertaining to the purpose, implementation, maintenance, and use of the registry).

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2011, and such sums as may be necessary for each of fiscal years 2012 through 2016.

TITLE II—EXPANSION AND ACCELERATION OF RESEARCH FOR GENOMICS AND PERSONALIZED MEDICINE

Subtitle A—Acceleration of Genomics and Personalized Medicine Research

SEC. 201. GRANTS FOR RESEARCH IN GENOMICS AND PERSONALIZED MEDICINE.

(a) IN GENERAL.—The Secretary, acting through the Directors of the Centers for Disease Control and Prevention and other relevant agencies (as determined by the Secretary), shall increase and accelerate research and programs to collect, evaluate, and disseminate genetic and genomic data that will advance the field of genomics and personalized medicine, which may include—

(1) studies of diseases and health conditions with substantial public health impact;

(2) population-based studies of genotype prevalence, gene-disease association, gene-drug response association, and interactions between genes and the environment;

(3) systematic review and synthesis of the results of population-based studies using methods of human genome epidemiology;

(4) translation of genomic information into molecular genetic and genomic screening tools, diagnostics, and therapeutics by supporting processes and studies that lead to effective and safe applications in clinical and public health practice;

(5) translation of genomic information into tools for public health investigations and ongoing biosurveillance and monitoring;

(6) comprehensive studies of clinical utility, including cost-effectiveness and cost-benefit analyses, of molecular genetic and genomic tests and therapeutics;

(7) implementation and postimplementation research to facilitate studies for evaluating effectiveness and utility in clinical and policy decision-making;

(8) comprehensive studies of clinical and laboratory practices necessary to ensure effective imple-

mentation of high-quality standards of practice using evidence-based clinical and public health guidelines for genetic and genomic tests;

(9) systematic review of data on analytic validity, clinical validity, and clinical utility of products used for personalized medicine, and data on implementation and dissemination of evidence-based practices;

(10) studies to assess the awareness, knowledge, and use of products used for personalized medicine and their impact on population health and health disparities;

(11) bioinformatics research designed to integrate genomics and personalized medicine into clinical practice; and

(12) research to fill gaps in clinical knowledge as determined by the CEGAPP.

(b) GRANTS.—

(1) IN GENERAL.—The Secretary may award grants to eligible entities to carry out the activities described in subsection (a).

(2) PRIORITY.—In awarding grants under this subsection, the Secretary shall give priority to eligible entities that—

(A) enter into collaborative research with public and private entities; or

(B) propose to address priorities identified by the CEGAPP under subtitle B.

(3) DEFINITION.—In this subsection, the term ''eligible entity'' includes any nonprofit organization with expertise in genomics and personalized medicine.

SEC. 202. NATIONAL BIOBANK.

(a) IN GENERAL.—The Director of the National Institutes of Health, in consultation with the Director of Centers for Disease Control and Prevention, shall establish and maintain a national biobank to advance the field of genomics and personalized medicine. The Director shall coordinate activities under this section with the activities of other public or private biobank or genomic database initiatives, including initiatives funded under section 203. The national biobank shall be designed to collect and integrate human biological specimens and biobank data for research purposes associated with genomics and personalized medicine.

(b) REQUIREMENTS.—In carrying out subsection (a), the Director of the National Institutes of Health shall—

(1) establish, directly or by contract, a single point of authority to manage operations of the national biobank;

(2) establish and disseminate quality standards and guidelines for the collection, processing, archiving, storage, and dissemination of human biological specimens and biobank data for research and clinical purposes;

(3) develop and promulgate guidelines regarding procedures, protocols, and policies for the safeguarding of the privacy of human biological specimens and biobank data, in accordance with applicable Federal and State regulations, guidelines, and policies, as appropriate;

(4) review and make recommendations to address ownership, patient access issues, and analyses with respect to human biological specimens and biobank data;

(5) develop and promulgate guidelines regarding procedures, protocols, and policies for access to human biological specimens and biobank data by nongovernmental entities for research purposes;

(6) develop and disseminate guidelines for structuring informed consent forms that address—

(A) privacy and confidentiality of human biological specimens and biobank data;

(B) understanding of research procedures, benefits, risks, rights, and responsibilities;

(C) continuous voluntary participation;

(D) the development of informed consent agreements that allow for future research in advance of clear research objectives; and

(E) the right of an individual to opt out of research at any time;

(7) develop mechanisms for informing the public about the national biobank;

(8) ensure the inclusion of underrepresented populations with health disparities in the activities of the national biobank, pursuant to the goals of Healthy People 2010;

(9) incorporate human biological specimens and biobank data from federally conducted or supported genomics initiatives, as feasible;

(10) encourage voluntary submission of human biological specimens and biobank data obtained or analyzed with private or non-Federal funds;

(11) facilitate submission of biobank data, including secure and efficient electronic submission;

(12) allow public use of human biological specimens and biobank data only—

(A) with appropriate privacy safeguards in place; and

(B) for research purposes;

(13) determine appropriate procedures for access by nongovernmental entities to human biological specimens and biobank data for research and development of new or improved tests and treatments, and submission of data generated from research and development to the Food and Drug Administration or appropriate agencies as part of the approval process for products used for personalized medicine;

(14) conduct, directly or by contract, analytical research, including clinical, epidemiological, and social-science, using human biological specimens and biobank data including the development of a long-term population cohort for investigating genetic and environmental health impacts; and

(15) make aggregate research findings from biobank initiatives supported by Federal funding publicly available within an appropriate timeframe (as determined by the Secretary).

SEC. 203. BIOBANK INITIATIVE GRANTS.

(a) IN GENERAL.—The Secretary shall establish a program of awarding grants to eligible entities for the development or expansion of a biobank initiative for the purposes of—

(1) increasing understanding of how genomics interacts with lifestyle factors and the environment to cause disease;

(2) examining the effectiveness of using genomic information in health management and medical decisionmaking;

(3) discovering genomic variations that affect drug toxicity and efficacy; and

(4) accelerating the development of products used for personalized medicine.

(b) USE OF FUNDS.—As a condition on receipt of a grant under subsection (a), an eligible entity shall agree to use the grant, consistent with the purposes described in such subsection, to develop or expand a biobank initiative. Such development or expansion may include any of the following activities:

(1) Support for the scientific community and medical advisory committees.

(2) Recruitment and education of diverse participants, especially underrepresented races,

ethnicities, and genders pursuant to the goals of Healthy People 2010.

(3) Development of consent protocols.

(4) Provision of genetic counseling services to participants, as appropriate.

(5) Obtaining human biological specimens and biobank data.

(6) Obtaining necessary equipment for data collection, analysis, and storage.

(7) Establishment and maintenance of secure storage for human biological specimens and biobank data.

(8) Conducting data analyses and evidence-based systematic reviews that allow for the following:

(A) Identification of biomarkers and other surrogate markers to improve predictions of onset of disease, response to therapy, and clinical outcomes.

(B) Increased understanding of gene and environment interactions.

(C) Development of personalized medicine screening, diagnostic, and therapeutic interventions.

(D) Genotypic characterization of human biological specimens and biobank data.

(9) Development of protocols for providing to health care providers and patients, by means of electronic health records in accordance with title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.), genomic information obtained during the course of research or treatment, for the purpose of improving patient care and outcomes.

(10) Development of interactive, Web-based portals to provide participants access to their personal genetic profile.

(11) Any other related activities deemed appropriate by the Secretary.

(c) BIOBANK REQUIREMENTS.—The Secretary shall ensure that any biobank supported under this section—

(1) supports genomics and personalized medicine research;

(2) adheres to standards, guidelines, and recommendations developed under section 202(b);

(3) is established to complement activities related to the implementation of current public biobank research initiatives, as feasible;

(4) is based on well-defined populations, including population-based registries of disease and family-based registries;

(5) collects data from participants with diverse genomic profiles, demographics, environmental exposures, and presence or absence of diverse health conditions and diseases, as appropriate;

(6) has practical experience and demonstrated expertise in genomics and its clinical and public health applications;

(7) establishes mechanisms to ensure patient privacy and protection of information from non-health applications and, as feasible, patient access to human biological specimens and biobank data for clinical testing purposes; and

(8) contributes biobank data to the national biobank established under section 202.

(d) PRIORITY.—In awarding grants under this section, the Secretary shall give priority to eligible entities with experience in conducting population-based genetic research studies (such as focused whole genome, and epigenetics studies) or genomic research on heritable or somatic mutations.

(e) QUALITY ASSURANCE.—The Secretary may enter into a contract with an external entity to evaluate grantees under this section to ensure that quality standards established under section 202(b) are met.

(f) APPLICATION OF PRIVACY RULES.—Nothing in this section shall be construed to supersede the requirements for the protection of patient privacy under—

(1) HIPAA privacy and security law (as defined in section 3009(a) of the Public Health Service Act (42 U.S.C. 300jj–19(a));

(2) sections 552 and 552a of title 5, United States Code (5 U.S.C. App.);

(3) the Genetic Information Nondiscrimination Act of 2008 (Public Law 110–233);

(4) part 46 of title 45, Code of Federal Regulations (or any successor regulations); or

(5) part 50 of title 21, Code of Federal Regulations (or any successor regulations).

(g) DEFINITION.—In this section, the term ''eligible entity'' includes an academic medical center, a university, a private nonprofit biomedical research institution, and any other entity determined appropriate by the Secretary.

SEC. 204. AUTHORIZATION OF APPROPRIATIONS.

To carry out this subtitle, there are authorized to be appropriated $150,000,000 for fiscal year 2011, and such sums as may be necessary for each of fiscal years 2012 through 2016.

Subtitle B—Committee on the Evaluation of Genomic Applications in Practice and Prevention

SEC. 211. ESTABLISHMENT.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish (pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217(a)) an advisory committee, composed of members from the public and private sectors, to expand and accelerate knowledge related to the clinical validity and utility of genomics and personalized medicine through the analysis of current literature, and determination of gaps in evidence. Such committee shall be known as the Committee on the Evaluation of Genomic Applications in Practice and Prevention.

(b) DUTIES.—The CEGAPP shall expand the breadth of knowledge related to the clinical validity and utility of genomics and personalized medicine by—

(1) establishing, testing, and publishing processes and methods for evidence-based reviews and recommendation development that are optimized for genetic and genomic tests and other products used for personalized medicine in transition from research to clinical and public health practice;

(2) identifying, prioritizing, and selecting topics for systematic evidence-based review;

(3) publishing evidence-based reviews and recommendations for clinical practice and areas for additional research for such topics;

(4) publishing experiences with systematic evidence-based review;

(5) publishing gaps in knowledge, as determined through reviews and recommendations under paragraph (3), to assist in carrying out section 201;

(6) integrating existing recommendations on implementation of genetic and genomic tests and other products used for personalized medicine from professional organizations and advisory committees;

(7) integrating knowledge and experience gained from existing processes for evaluation and appraisal, previous public and private initiatives, and the international health technology assessment experience;

(8) advising the Centers for Medicare & Medicaid Services on whether current evidence supports the coverage of specific products used for personalized medicine (including genetic and genomic tests used for the screening of diseases in cases where a family history of such disease is present);

(9) developing or adapting processes for recognizing promising new products used for personalized medicine and supporting their translation to clinical and public health practice; and

(10) developing processes for the collection of data reflective of analytic and clinical validity and utility and quality measures indicative of good clinical and laboratory practices for tests early in their translation or adoption cycle.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $5,000,000 for fiscal year 2011, and such sums as may be necessary for each of fiscal years 2012 through 2016.

TITLE III—GENOMICS AND PERSONALIZED MEDICINE IN CLINICAL PRACTICE AND PUBLIC HEALTH

SEC. 301. GENOMICS AND PERSONALIZED MEDICINE EDUCATION AND TRAINING.

(a) IN GENERAL.—The Secretary shall make grants, contracts, or cooperative agreements to eligible entities to improve the adequacy of genomics and personalized medicine training for specimen collection, diagnosis, treatment, and counseling of adults and children for both rare and common disorders, through support of efforts to—

(1) develop and disseminate model education and training programs across all health professionals, including medical student, graduate medical, and continuing education, that reflect the new knowledge and evolving practice of genetics and genomics including the appropriate use of products used in personalized medicine;

(2) assist with the review of board and other certifying examinations by professional societies and accreditation bodies to ensure adequate focus on the fundamental principles of genomics and personalized medicine and applications to clinical decisionmaking;

(3) identify, evaluate, and develop options for distance or online learning for degree or continuing education programs;

(4) identify gaps and opportunities to strengthen continuing education programs for health care professionals;

(5) develop and disseminate model programs to train pathologists on the specialized mechanisms of collection and storage of human biological specimens for biobanks; and

(6) develop exchange programs for student, residents, and fellows to learn techniques and prac-

tices to augment genomics and personalized medicine.

(b) INTEGRATION.—The Secretary, in consultation with medical professional societies, accreditation bodies, associations of health professional schools, and other public and private entities, shall support initiatives to increase the integration of genomics and personalized medicine into all aspects of clinical and public health practice by promoting genomics and personalized medicine competency across all clinical, public health, and laboratory disciplines through—

(1) the development and dissemination of health professional guidelines which shall—

(A) include focus on appropriate techniques for collection and storage of genomics samples, administration and interpretation of genetic and genomic tests, and subsequent clinical and public health decisionmaking; and

(B) specifically target health professionals without formal training or experience in the field of genomics;

(2) the development and dissemination of evidence-based clinical decision support tools for implementation at the point of care in consultation with

the Office the National Coordinator for Health Information Technology;

(3) the development, cataloging, and dissemination of case studies and practice models relating to the use of products of personalized medicine;

(4) the dissemination of both public and private systematic reviews on and technology assessments of the clinical validity and utility of products of personalized medicine in coordination with the CEGAPP to facilitate the development of clinical practice guidelines;

(5) the facilitation of the development of evidence-based clinical practice guidelines and dosing guidelines for product use for personalized medicine by supporting consensus-building efforts, which shall include—

(A) development of standards that define the minimal levels of evidence required to support guidelines decisions; and

(B) the clinical contexts (such as prevention, diagnosis, and treatment) in which genetic and genomic tests may be offered; and

(6) the encouragement of public and private sector entities to submit clinical practice guidelines on products of personalized medicine to federally es-

tablished clinical practice guidelines clearinghouses to facilitate dissemination and encourage implementation and use of such guidelines.

(c) DEFINITION.—In this section, the term ''eligible entity'' includes any professional genetics and genomics society, accreditation body, health care professional organization, academic institution, and any other entity as determined appropriate by the Secretary.

(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $30,000,000 for fiscal year 2011, and such sums as may be necessary for each of fiscal years 2012 through 2016.

TITLE IV—REALIZING THE POTENTIAL OF PERSONALIZED MEDICINE

SEC. 401. REDUCING THE REDUNDANCY OF CLINICAL LABORATORY REQUIREMENTS.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Centers for Medicare & Medicaid Services and the Commissioner of Food and Drugs, shall establish a committee to carry out a comparative analysis of laboratory review requirements under CLIA to—

(1) assess and reduce unnecessary differences in such requirements; and

(2) identify opportunities to eliminate redundancies and decrease the burden of review, as practicable, of the Centers for Medicare & Medicaid Services, the Food and Drug Administration, and private laboratory certifying entities.

(b) REPRESENTATION.—The membership of the committee established under this section shall include representatives of the agencies of the Public Health Service, other appropriate Federal departments and agencies, private laboratories, and private laboratory accreditation organizations.

(c) PUBLIC INPUT.—The Secretary shall conduct open public meetings and develop a process to allow for public comment on such comparative analysis.

(d) REPORTING.—The Secretary shall require the committee established under this section to submit—

(1) a draft report on such comparative analysis, including recommendations on opportunities identified under subsection (a)(1), to the Secretary not later than 12 months after the date of the enactment of this Act; and

(2) a final such report to the Secretary not later than 24 months after such date.

SEC. 402. COMMITTEE ON PUBLIC ENGAGEMENT.

(a) IN GENERAL.—The Secretary shall establish a committee, to be composed of representatives from the private sector who are engaged in genomics and personalized medicine, to—

(1) examine barriers in research, regulation, and reimbursement to innovation, development, and implementation of medical product development for personalized medicine and the impact of such barriers; and

(2) make recommendations to address such barriers.

(b) COLLABORATION WITH OPH.—The Secretary shall ensure that, to the extent possible, such committee carries out this section in collaboration with the OPH.

(c) REPORTING.—The Secretary shall require such committee to submit a draft report on the committee's recommendations under subsection (a)(2) to the Secretary not later than 24 months after the date of the enactment of this Act and annually thereafter.

SEC. 403. STUDY BY THE INSTITUTE OF MEDICINE.

(a) IN GENERAL.—The Secretary shall enter into an agreement with the Institute of Medicine, in consultation with public and private sector entities involved in personalized medicine, to provide an independent, external review of the current billing, coverage, and reimbursement meth-

odologies for products and services used for personalized medicine (including genetic and genomic tests).

(b) REQUIREMENTS.—The agreement under subsection (a) shall provide for preparation of a report by the Institute of Medicine. Such report shall include—

(1) a review of the current billing, coverage, and reimbursement policies for products and services used for personalized medicine (including genetic and genomic tests);

(2) specific recommendations for billing, coverage, and reimbursement models by public and private insurers that promote research and development of products used for personalized medicine (including genetic and genomic tests), taking into account the overall impact of such products on patient outcomes (as demonstrated by evidence from clinical trials and other well-designed empirical studies), the value of such products to the health care system, market-based pricing of such products, and savings accrued from test utilization to the health care system through disease management and early diagnosis;

(3) recommendations for clinical trial designs to provide evidence sufficient to support coverage of products used for personalized medicine (including

genetic and genomic tests) by public and private payors, including reimbursement during the evidence development phase of well-designed studies;

(4) recommendations for the reimbursement of health care professionals providing genetic counseling services to—

(A) define which health professionals, taking into consideration certification, licensure, and training and scope of practice under State law, are qualified to provide genetic counseling services;

(B) define which professionals should be able to practice, consistent with their scope of practice under State law, without physician supervision, direction, responsibility, or control, and, thereby, bill payers directly for their services; and

(C) assess the adequacy of existing current procedural terminology evaluation and management codes and their associated relative values with respect to genetic counseling services;

(5) recommendations for appropriate mechanisms to promote research and development to advance personalized medicine (which may include tax

credits, grant programs, or extensions of patent or exclusivity) to include costs and benefits to society;

(6) incentives to encourage development of products used for personalized medicine, including development of genetic and genomic tests for patients with rare disorders;

(7) criteria for defining when a family history should be considered a personal history of disease for reimbursement purposes under title XVIII of the Social Security Act; and

(8) identification or recommendations regarding such other issues as determined appropriate by the Secretary.

(c) STAKEHOLDER INPUT.—The agreement under subsection (a) shall require the Institute of Medicine, in preparing the report under this section, to work in consultation with each category of public and private stakeholders involved in personalized medicine, including genomics and personalized medicine consumers, physicians and other health care providers including pathologists, scientists and researchers, private payors, representatives from clinical and academic laboratories, and representatives from the biotechnology, pharmaceutical, and diagnostics industries.

(d) REPORT.—Not later than 12 months after the date of the enactment of this Act, the Secretary shall submit the report prepared under this section to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives.

SEC. 404. FOOD AND DRUG ADMINISTRATION.

(a) ENCOURAGEMENT OF COMPANION DIAGNOSTIC TESTING.—The Secretary, acting through the Commissioner of Food and Drugs, may require the sponsor of a drug or biological product—

(1) to develop a companion diagnostic test in connection with the submission of an investigational new drug application or a new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to address significant safety concerns of the drug or biological product;

(2) to develop a companion diagnostic test if data from postmarketing clinical trials demonstrate significant safety or effectiveness concerns with use of the drug or biological product and include in the label of the drug or biological product a recommendation to use a companion diagnostic test if data demonstrate—

(A) significant safety concerns with the drug or biologic product; and

(B) improved outcomes with the administration of a companion diagnostic test; and

(3) to conduct additional postmarket studies to identify genetic and other biological, social, behavioral, and environmental factors that may underlie the differential drug effects when drugs are shown to be more or less effective in certain racial and ethnic subpopulations.

(b) CLARIFICATION AND GUIDANCE.—The Secretary, acting through the Commissioner of Food and Drugs, shall clarify and issue guidance regarding—

(1) the criteria and procedures for determining when labeling of a product used for personalized medicine will incorporate information on related companion diagnostic tests, as well as establish the circumstances under which such tests will be either recommended or required;

(2) the standards of evidence that must be met for information pertaining to pharmacogenomics (as defined in section 2) to be included in the label of a product used for personalized medicine, such as with respect to the analytical validity, clinical validity, clinical utility, dosing, adverse events, and drug

selection, for use by clinicians when making treatment decisions based on the results of genetic and genomic tests;

(3) the regulation of automated clinical decision support systems; and

(4) the collection and analysis of genetic and other biological factors that may be better biological predictors of individual differences in drug response than broad categories such as race, ethnicity, and gender.

SEC. 405. ADVERSE EVENTS.

The Secretary, in consultation with the Commissioner of Food and Drugs and the Administrator of the Centers for Medicare & Medicaid Services, shall—

(1) facilitate the use of products used for personalized medicine, as feasible, to assess risk for, and reduce incidence of, adverse drug reactions;

(2) develop or expand adverse event reporting systems to encompass reports of adverse events resulting from products used for personalized medicine, including laboratory developed test; and

(3) develop systems to appropriately respond to any adverse events resulting from products used for personalized medicine.

SEC. 406. TERMINATION OF CERTAIN ADVERTISING CAMPAIGNS.

The Commissioner of Food and Drugs shall collaborate with the Federal Trade Commission to identify and terminate, pursuant to section 5 of the Federal Trade Commission Act (15 U.S.C. 45), advertising campaigns that make false, misleading, deceptive, or unfair claims about the benefits or risks of products used for personalized medicine.

SEC. 407. CENTERS FOR DISEASE CONTROL AND PREVENTION.

(a) PUBLIC AWARENESS.—The Director of the Centers for Disease Control and Prevention shall expand efforts to educate and increase awareness of the general public about genomics and personalized medicine and its applications to improve health, prevent disease, and eliminate health disparities. Such efforts shall include—

(1) ongoing development and dissemination of evidence-based informational resources and materials on the validity and utility of products used for personalized medicine (including genetic and genomic tests);

(2) ongoing collection of data on the awareness, knowledge, and use of genetic and genomic tests through public health surveillance systems, and analysis of the impact of such tests on population health;

(3) integration of the use of validated genetic and genomic tests in public health programs, as appropriate; and

(4) evaluation of laboratory standards and practices for quality laboratory services.

(b) DIRECT-TO-CONSUMER MARKETING.—Not later than 12 months after the date of the enactment of this Act, the Director of the Centers for Disease Control and Prevention, in conjunction with the Food and Drug Administration and the Federal Trade Commission, with respect to products used for personalized medicine (including genetic and genomic tests) for which consumers have direct access, shall—

(1) conduct an analysis of the public health impact of direct-to-consumer marketing to the extent possible from available data sources;

(2) analyze the validity of claims made in direct-to-consumer marketing to determine whether such claims are substantiated by competent and reliable scientific evidence; and

(3) make recommendations to the Secretary regarding necessary interventions to protect the public from potential harms of direct-to-consumer marketing and access to products used for personalized medicine (including genetic and genomic tests).

SEC. 408. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—To carry out sections 403, 404, 405, and 406, there are authorized to be appropriated $40,000,000 for fiscal year 2011, and such sums as may be necessary for each of fiscal years 2012 through 2016.

(b) REDUCING THE REDUNDANCY OF CLINICAL LABORATORIES.—To carry out section 401, there are authorized to be appropriated $5,000,000 for fiscal year 2011, and such sums as may be necessary for fiscal year 2012.

(c) COMMITTEE ON PUBLIC ENGAGEMENT.—To carry out section 402, there are authorized to be appropriated $1,000,000 for fiscal year 2011, and such sums as may be necessary for each of fiscal years 2012 through 2016.

(d) CDC PUBLIC AWARENESS ACTIVITIES.—To carry out section 407, there are authorized to be appropriated $20,000,000 for fiscal year 2011, and such sums as may be necessary for each of fiscal years 2012 through 2016.

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